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POPOVICH, WILES & O'CONNELL, PA			KIFLE, BRUCK	
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MINNEAPOLI	MINNEAPOLIS, MN 55402		1624	
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Please find below and/or attached an Office communication concerning this application or proceeding.

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Application No. Applicant(s) 10/647,283 CZOLLNER ET AL. Office Action Summary Examiner Art Unit Bruck Kifle, Ph.D. 1624 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). **Status** 1) Responsive to communication(s) filed on 17 August 2005. 2a) This action is **FINAL**. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. **Disposition of Claims** 4) Claim(s) 1-7 is/are pending in the application. 4a) Of the above claim(s) 2-7 is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) ☐ Claim(s) 1 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) ____ are subject to restriction and/or election requirement. **Application Papers** 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 09/242,339. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date. _ Notice of Informal Patent Application (PTO-152) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 08/26/03. 6) Other: U.S. Patent and Trademark Office

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Election/Restrictions

Applicant's election of group I in the reply filed on 08/17/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- i) In the definitions of the variables, the term "substituted" appears numerous times without specifying the substituents which is indefinite because one cannot say which substituents are intended and which ones are not.
- ii) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites:

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a) in the definition of R_1 , the broad recitation "substituted lower alkyl," and also recites "- $(CH_2)_n$ -Cl, - $(CH_2)_n$ -Br, - $(CH_2)_n$ -OH, - $(CH_2)_n$ -COOH, - $(CH_2)_n$ -CN, - $(CH_2)_n$ -NC" which is the narrower statement of the range/limitation;

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- b) in the definition of R₁, the broad recitation "alkoxy carbonyl," and also recites "COO alkyl" which is the narrower statement of the range/limitation. and COO alkyl;
- c) in the definition of R₃, the broad recitation "alkoxy," and also recites "OCH₃" which is the narrower statement of the range/limitation.
- iii) In claim 1, R_1 and R_2 are defined as "-(CH₂)_n-Cl, -(CH₂)_n-Br, -(CH₂)_n-OH, -(CH₂)_n-COOH, -(CH₂)_n-CN, -(CH₂)_n-NC, in which". This is incomplete.
- iv) In the definition "R₂-R₃ can jointly form: -O-(CH₂)_n-O-, with N=1 to 3;" it appears that "n" may have been intended. Appropriate correction is required. Also, would this "n" be applicable to each occurrence?
- v) In claim 1, the variable R₇ is not defined.
- vi) The definition of R_4 and R_5 is confusing. If Applicants intend that these groups are independent, language such as, " R_4 and R_5 are independently selected from the group consisting of hydrogen, alkyl," is suggested.
- vii) In page 3 of claim 15, "O-protective group" is present. It is unclear what this group is and what the O is supposed to be protected against (bases, acids, heat, amides?).
- viii) The group O-CS-N-R₈ is followed by thiourethans in parentheses. The formula fully describes the substituent and examples are improper in a claim.

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- ix) In the group O-CO-R₈, the definition of R₈ does not permit the three groups depicted. Also, the term "including" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).
- x) In the definition of R_4 and R_5 in the middle of page 87, the formula define the hydrazone and oximes so the terms are superfluous and inaccurate. Also, the formula -N=N(R_{10} , R_{11}) should be correctly rewritten as -N=NR₁₀R₁₁ because both R groups are attached to the nitrogen.
- xi) The phrase "as well as" in page 3 renders the claim indefinite.
- xii) The group "sulfonic acid" group cannot be a substituent because it is a compound and not a radical. If Applicants intend the radical -SO₃H, then so should be stated.
- xiii) The top of page 88 states "wherein Y_1 , $Y_2 = O$, S, NH or N-R₁₀ (excess valences in each case are -H". Applicants should fully define these variables as, for example, "Y₁ represents O, S, NH or NR₁₀; Y₂ represents -OH, -SH, -NH₂ or NHR₁₀".
- xiv) In the definition of R_4 and R_5 , the group -C(R_{15} , R_{16})- should be rewritten as -C($R_{15}R_{16}$)- as pointed in point (x) above to be of correct chemical form.
- xv) The second formula on the top of page 89 is a phenylene group where is stated "that is an ortho, meta or para disubstituted aromatic". The substituents are not given.
- xvi) In the fifth line on page 5, "P = 1" is present. What does this refer to?
- xvii) The phrase "Compounds of the general formula (II)" renders the claim open-ended and is not proper language. The phrase "A compound of formula (I)" is suggested. The structural formula along with the definitions of the variables fully will define the compound claimed. By claiming the compounds in the alternative, the suggested language is of proper form.

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xviii) In the definition of R₁ and R₂, the group CONH and CON alkyl are present. These groups have open valencies. Appropriate correction is required (e.g. CONH₂, CON(alkyl)₂, if this is what is intended).

xix) In the definition of R_4 and R_5 as =N-NH-C(Y₁)-Y₂ and =N-NH-C(Y₁)-COOR_a, the group R_a is not defined. d) It is unclear how G_1 and G_2 can jointly be an alkyl spiro group.

xx) In the definition of R_{21} as "heteroaryl" it is unclear how many atoms are present, how many and what kind of heteroatoms are involved, what size ring is intended and how many rings are present.

xxi) The variable R_7 is not defined.

xxii) It is unclear how G_1 and G_2 can jointly be an alkyl spiro group.

xxiii) The variable "Z" is defined as N or N^+ . However, "N" is not permitted here because of the four bonds creating the quaternary N^+ with a required counter ion. Appropriate correction is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle, Ph.D. whose telephone number is 571-272-0668.

The examiner can normally be reached Tuesdays to Fridays between 8:30 AM and 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bruck Kifle, Ph.D. Primary Examiner

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August 24, 2005